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10/578,530	02/01/2007	Sergei Gryaznov	074/002	5144

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
06/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,530	GRYAZNOV ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *42-74* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Preliminary Amendment filed May 3, 2006.

Claims 1-41 have been canceled. New claims 42-74 are acknowledged.

Claims 42-74 are pending in the instant application.

Claims 42-74 are subject to restriction as detailed below:

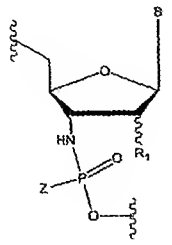
Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 42-46 and 57-74, drawn to a small interfering RNA (siRNA) comprising 15-25 nucleotide complementary to a target nucleic acid sequence, wherein the RNA comprises at least one internucleoside linkage chosen from ribo-N3'→P5' phosphoramidate (NP) and ribo-N3'→P5' thiophosphoramidate (NPS) linkages, classifiable in class 536, subclass 24.5, for example. **If this Group is elected, a further restriction is required for claims 63, 65, 67, 69, 71, and 73.**

II. Claims 47-51, drawn to a compound comprising the structure: O-(x-L)n, wherein:

- O is a riboamidate of formula:

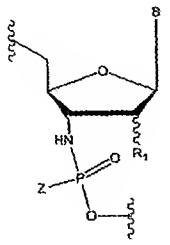


classifiable in class 536, subclass 24.5, for example.

III. Claims 52-54, drawn to a method for effecting the post-transcriptional silencing of at least one gene, comprising administering to a mammal in need of such post-transcriptional silencing at least one small interfering RNA (siRNA) comprising 15-25 nucleotide complementary to a target nucleic acid sequence, wherein the RNA comprises at least one internucleoside linkage chosen from ribo-N3'→P5' phosphoramidate (NP) and ribo-N3'→P5' thiophosphoramidate (NPS) linkages, classifiable in class 514, subclass 44, for example. **If this Group is elected, a further restriction is required for claim 54.**

IV. Claims 55 and 56, drawn to a method for effecting the post-transcriptional silencing of at least one gene, comprising administering to a mammal in need of such post-transcriptional silencing at least one compound comprising the structure: O-(x-L)n, wherein:

- Q is a riboamidate of formula:



classifiable in class 514, subclass 44, for example. **If this Group is elected, a further restriction is required for claim 56.**

The inventions are distinct, each from the other, because of the following reasons:

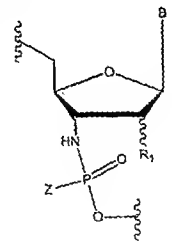
Group I is related to Group III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the small interfering RNA (siRNA) comprising 15-25 nucleotide complementary to a target nucleic acid sequence, wherein the RNA comprises at least one internucleoside linkage chosen from ribo-N3'→P5' phosphoramidate (NP) and ribo-N3'→P5' thiophosphoramidate (NPS) linkages of Group I can be used in materially different processes such as a hybridization probe in a method of identifying target gene expression *in situ*, which is a materially different process than the method for effecting the post-transcriptional silencing of at least one gene, comprising administering to a mammal in need of such post-transcriptional silencing at least one small interfering RNA (siRNA) comprising 15-25 nucleotide

complementary to a target nucleic acid sequence, wherein the RNA comprises at least one internucleoside linkage chosen from ribo-N3'→P5' phosphoramidate (NP) and ribo-N3'→P5' thiophosphoramidate (NPS) linkages of Group III. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

Group II is related to Group IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compound comprising the structure: O-(x-L)n of Group II can be used in materially different processes such as a hybridization probe in a method of identifying target gene expression *in situ*, which is a materially different process than the method for effecting the post-transcriptional silencing of at least one gene, comprising administering to a mammal in need of such post-transcriptional silencing at least one compound comprising the structure: O-(x-L)n of Group IV. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

Searching the inventions of Groups I and II would impose a serious search burden because the inventions of Groups I and II are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the invention of Groups I and II are unrelated and distinct because they are materially distinct compositions such that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the small interfering RNA (siRNA) comprising 15-25 nucleotide complementary to a target nucleic acid sequence, wherein the RNA comprises at least one internucleoside linkage chosen from ribo-N3'→P5' phosphoramidate (NP) and ribo-N3'→P5' thiophosphoramidate (NPS) linkages of Group I would not necessarily encompass all of the art relevant to the a compound

- O is a riboamidate of formula:



comprising the structure: O-(x-L)n, wherein: of Group II. Since the search for Group I is not entirely coextensive with a search for Group II, it would be burdensome to search the inventions of these Groups together in one application. It is therefore a burden to search the invention of Group I together with the invention of Group II in a single application.

Group III is drawn a method for effecting the post-transcriptional silencing of at

least one gene, comprising administering to a mammal in need of such post-transcriptional silencing at least one small interfering RNA (siRNA) comprising 15-25 nucleotide complementary to a target nucleic acid sequence, wherein the RNA comprises at least one internucleoside linkage chosen from ribo-N3'→P5' phosphoramidate (NP) and ribo-N3'→P5' thiophosphoramidate (NPS) linkages and is considered to be distinct from the method for effecting the post-transcriptional silencing of at least one gene, comprising administering to a mammal in need of such post-transcriptional silencing at least one compound comprising the structure: O-(x-L)n of Group IV. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of Group III is distinct from the method of Group IV since the method of Group III recites distinct method steps and distinct objectives, with the use of distinct compositions, apart from the method steps and objectives recited in Group IV. Furthermore, Group III is distinct from Group IV since the invention of Group III does not overlap in scope with that of Group IV since each Group set recites materially distinct methods which differ in criteria for success. Because these Group sets utilize unique and different method steps, with unique compositions used in the methods steps, the inventions are also therefore not obvious variants, and have a materially different design. Furthermore, because these Group sets utilize unique and different method steps, the prior art applicable to one Group set

would not likely be applicable to another Group set and the inventions in each Group set are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. Accordingly, restriction between these Groups is considered proper.

If Group I is elected, claims 63, 65, 67, 69, 71, and 73 are subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 63, 65, 67, 69, 71, and 73 specifically claim a small interfering RNA (siRNA) comprising 15-25 nucleotide complementary to a target nucleic acid sequence, wherein the RNA comprises at least one internucleoside linkage chosen from ribo-

N3'→P5' phosphoramidate (NP) and ribo-N3'→P5' thiophosphoramidate (NPS) linkages; wherein the target nucleic acid sequence is a human immunodeficiency virus gene; wherein the target nucleic acid sequence is a beta site APP-cleaving enzyme (BACE) gene; wherein the target nucleic acid sequence is a EGFR gene; wherein the target nucleic acid sequence is a K-ras gene; wherein the target nucleic acid sequence is a PTGDR gene; and wherein the target nucleic acid sequence is an ADORA1 gene, respectively. Although the siRNA are complementary to a target nucleic acid sequence, the instant siRNA are considered to be unrelated, since each target nucleic acid sequence claimed is structurally and functionally independent and distinct for the following reasons: each a target nucleic acid sequence is a unique nucleotide sequence, each a target nucleic acid sequence is specific for a different gene, each target nucleic acid sequence is associated with a different disease, and each siRNA will modulate the expression of a different target nucleic acid sequence (As per Applicant's disclosure at pages 14 and 15 in the instant specification). As such the Markush/genus of siRNA in claims 63, 65, 67, 69, 71, and 73 are not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the siRNA claimed in claims 63, 65, 67, 69, 71, and 73 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed siRNA. In view of the foregoing, one (1) siRNA targeted to one (1) target nucleic acid sequence is considered to be a reasonable number of sequences for examination. Accordingly, if Applicants elect Group I, Applicants are required to elect **one (1)** target nucleic acid sequence from

claims 63, 65, 67, 69, 71, and 73. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally distinct target nucleic acid sequences.

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If Group III is elected, claim 54 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 54 specifically claims a method for effecting the post-transcriptional silencing of at least one gene, comprising administering to a mammal in need of such

post-transcriptional silencing at least one small interfering RNA (siRNA) comprising 15-25 nucleotide complementary to a target nucleic acid sequence, wherein the RNA comprises at least one internucleoside linkage chosen from ribo-N3'→P5' phosphoramidate (NP) and ribo-N3'→P5' thiophosphoramidate (NPS) linkages, wherein the at least one gene is a cellular mRNA, a viral mRNA, or an oncogene mRNA. Although the method will effect the post-transcriptional silencing of at least one gene, the instant genes are considered to be unrelated, since each method for effecting the post-transcriptional silencing of at least one gene claimed is structurally and functionally independent and distinct for the following reasons: each gene is entirely different, each from the other, and each gene is associated with a different disease (As per Applicant's disclosure at pages 14 and 15 in the instant specification). As such the Markush/genus of methods for effecting the post-transcriptional silencing of at least one gene claim 54 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the methods for effecting the post-transcriptional silencing of at least one gene claimed in claim 54 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed genes. In view of the foregoing, one (1) gene is considered to be a reasonable number of sequences for examination. Accordingly, if Applicants elect Group III, Applicants are required to elect **one (1)** gene from claim 54. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally distinct genes.

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If Group IV is elected, claim 56 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 56 specifically claims a method for effecting the post-transcriptional silencing of at least one gene, comprising administering to a mammal in need of such post-transcriptional silencing at least one compound comprising the structure: O-(x-L)n, wherein the at least one gene is a cellular mRNA, a viral mRNA, or an oncogene mRNA. Although the method will effect the post-transcriptional silencing of at least one gene, the instant genes are considered to be unrelated, since each method for effecting

the post-transcriptional silencing of at least one gene claimed is structurally and functionally independent and distinct for the following reasons: each gene is entirely different, each from the other, and each gene is associated with a different disease (As per Applicant's disclosure at pages 14 and 15 in the instant specification). As such the Markush/genus of methods for effecting the post-transcriptional silencing of at least one gene claim 56 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the methods for effecting the post-transcriptional silencing of at least one gene claimed in claim 56 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed genes. In view of the foregoing, one (1) gene is considered to be a reasonable number of sequences for examination. Accordingly, if Applicants elect Group IV, Applicants are required to elect **one (1)** gene from claim 56. Note that this is not a species election but a restriction of distinct and independent inventions: unique and structurally distinct genes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Also, because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination

purposes as indicated is proper.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

June 18, 2009
/Terra Cotta Gibbs/